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| 10/758,997   | 01/16/2004  | Michael Nyle Hershberger | P155                | 7917             |
| 27752 7590 11/23/2009<br>THE PROCTER & GAMBLE COMPANY  |             |                          | EXAMINER            |                  |
| Global Legal Department - IP<br>Sycamore Building - 4th Floor<br>299 East Sixth Street<br>CINCINNATI, OH 45202 |             |                          | SCHLIENTZ, NATHAN W |                  |
|  |             |                          | ART UNIT            | PAPER NUMBER     |
|  |             |                          | 1616                | •                |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/758,997 HERSHBERGER MICHAEL NYLE Office Action Summary Examiner Art Unit Nathan W. Schlientz 1616 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 24 July 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-19.27-33 and 39 is/are pending in the application. 4a) Of the above claim(s) 8-14.27-33 and 39 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-7 and 15-19 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Status of Claims

Claims 1-19, 27-33 and 39 are pending in the present application. Claims 8-14.

27-33 and 39 are withdrawn from further consideration as being drawn to non-elected

subject matter. Therefore, claims 1-7 and 15-19 are examined herein on the merits for

patentability to the extent that they read on the elected subject matter of record. No

claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are

hereby withdrawn. The following rejections and/or objections are either reiterated or

newly applied. They constitute the complete set of rejections and/or objections presently

being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu
  et al. (US 2002/0025325) in view of Burkhalter et al. (The Journal of Nutrition, 2001),
  Sunvold et al. (Journal of Animal Science, 1995), Fahey et al. (Journal of Animal
  Science, 1990), Sunvold '258 (US 5,932,258), Jezek et al. (Chemical and Biochemical
  Engineering Quarterly, 1996), and Desforges et al. (US 5,252,136).

## Determination of the scope and content of the prior art (MPEP 2141.01)

Chu et al. teach compositions for oral vaccination of healthy animals through drinking water or syrups comprising admixing a palatable flavorant with a vaccine formulation in order to promote self-administration of the vaccine formulation and/or to prevent rejection of the formulation when administered by an animal handler (Abstract). Chu et al. teach an example wherein the lyophilized vaccine is re-suspended in a flavored diluent, mixed with 5 liters milk solution containing non-fat dry milk, and then further diluted with 7 liters of water ([0102]). Also, Chu et al. teach that flavorants for use in the vaccine formulations include fruit flavors preferred for horses, cats and dogs, meat flavors preferred for dogs and cats, and fish flavors preferred for cats ([0029]).

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## Ascertainment of the difference between the prior art and the claims

#### (MPEP 2141.02)

Chu et al. do not teach the addition of beet pulp to their composition, as instantly claimed. However, Burkhalter et al. teach that beet pulp is the most common source of fiber added to commercial dog diets (page. 1979, left column, lines 8-10 after the table description). Sunvold et al. teach that diets containing moderately fermentable fiber provide fermentation end products that may be important in maintaining the health of the gastrointestinal tract of the cat, and beet pulp represents a moderately fermentable fiber source (Abstract; pg. 2335, left column, last sentence; pg. 2338, left column, lines 40-55 without counting spaces). Fahey et al. teach beet pulp levels up to 7.5% of diet DM appear acceptable as a dietary fiber source in a meat-based canine diet (Abstract). Sunvold '258 teach beet pulp is a fermentable fiber which intestinal bacteria present in the animal can ferment to produce significant quantities of short-chain fatty acids (col. 3, II. 48-54). Jezek et al. teach the production of soluble dietary fibers from sugar beet pulp (Title and Abstract). Desforges et al. teach water-soluble fiber obtainable by treating sugar beet with water free from chemical reagents at ambient temperature and at an elevated temperature (Abstract). Desforges et al. further teach that commercial sources of dietary fiber from sugar beet pulp are known, wherein araban is one example of a fraction of the soluble fiber from sugar beet, and water-soluble beet fiber is also found in beet molasses (col. 1, l. 55 to col. 2, l. 5). Desforges et al. also teach that soluble sugar beet fiber has cholesterol lowering properties (i.e., hypocholestrolaemic Art Unit: 1616

effect), and a beneficial effect on blood glucose and mineral availability (col. 2, II. 13-

17).

#### Finding of prima facie obviousness

#### Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add beet pulp fiber to the composition of Chu et al. because beet pulp fiber is well-known as a commercial source of dietary fiber for use in pet foods, and soluble beet fiber has cholesterol lowering properties (i.e., hypocholestrolaemic effect), and a beneficial effect on blood glucose and mineral availability, as reasonably taught by Desforges et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

## Response to Arguments

Applicants argue on page 3 that Burkhalter et al., Sunvold et al., Fahey et al. and Sunvold '258 all teach extruded and dried food compositions, the objective of Desforges et al. is to produce a sugar composition, and Desforges et al. and Jezek et al. teach methods of production of dietary fiber from sugar beets. Thus, Applicants argue that Burkhalter et al., Sunvold et al., Fahey et al., Sunvold '258, Desforges et al. and Jezek et al. fail to teach incorporation of beet pulp into a liquid composition.

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However, the examiner respectfully argues that Burkhalter et al. teach that fiber is a nutritionally, chemically and physically heterogeneous material categorized into two major subclasses, i.e., soluble-viscous-fermentable fiber (soluble) and insolublenonviscous-nonfermentable fiber (insoluble) (pg. 1978, right column, In. 1-5). Sunvold et al. teach that beet pulp is a moderately fermentable fiber source and providing a source of moderately fermentable fiber in cats' diets promotes the formation of fermentation end products that may be important in maintaining the health of the lower gastrointestinal tract of cats. The addition of moderately fermentable fibers to cat diets can provide a source of fermentation end products important in the maintenance of gastrointestinal tract health, as well as excellent stool quality and nutrient digestibility (pg. 2338, left column, last two paragraphs). Jezek et al. teach that sugar beet pulp contains high quantity of dietary fibers; and the soluble fraction from the sugar beet pulp can reduce serum cholesterol, it can be used in hypertension therapy, as well as a replacement for sugar in cases of diabetes (Conclusion, para, 1 and 7). Desforces et al. teach that soluble beet fiber has cholesterol lowering properties, i.e. has a hypocholesterolaemic effect, and have a beneficial effect on blood glucose and mineral availability (col. 2, ln. 13-17). Therefore, it is clear from these teachings that the soluble fiber from beet pulp has numerous health benefits, and it would have been prima facie obvious for one of ordinary skill in the art to include the soluble beet pulp fiber in the liquid compositions according to Chu et al. in order to obtain these many health benefits associated with the soluble fermentable fiber.

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2. Claims 1-7 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tinembart et al. (US 2002/0058683) in view of Chu et al. (US 2002/0025325) and Burkhalter et al. (The Journal of Nutrition, 2001), Sunvold et al. (Journal of Animal Science, 1995), Fahey et al. (Journal of Animal Science, 1990), Sunvold '258 (US 5,932,258), Jezek et al. (Chemical and Biochemical Engineering Quarterly, 1996), and Desforges et al. (US 5,252,136).

# Determination of the scope and content of the prior art (MPEP 2141.01)

Tinembart et al. teach a veterinary preparation for fleas comprising lufenuron and nitenpyram, wherein oral administration of a liquid composition comprising lufenuron and nitenpyram effectively controlled flea infestation ([0057]-[-0058]). Tinembart et al. also teach that because of its simple practicability, oral usage is one of the preferred subjects of the invention, especially the administration of tablets or suspensions, wherein additives are used to encourage willing consumption by the host animal, such as suitable odorous substances, flavorings and/or taste substances ([0061]-[0063]). Tinembart et al. teach that the lufenuron and nitenpyram are present from 0.1-95 wt.% ([0078]). Tinembart et al. teach that the dosages may be carried in specially designed packs for administration by the veterinarian or keeper ([0075] and [0087]).

Furthermore, Tinembart et al. teach an emulsifier concentrate example comprising 20 wt.% active substances (i.e. lufenuron and nitenpyram), 20 wt.% emulsifier, and 60 wt.% solvent, and the composition is diluted with water to the desired

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concentration (Example 6). Also, Tinembart et al. teach drink additive examples comprising 15 wt.% of active ingredient, 10 wt.% of the active ingredient in diethylene glycol monoethylether, 10 wt.% in polyethylene glycol 300, and 5 wt.% in glycerol (Example 7).

The teachings Chu et al. are discussed above and incorporated herein by reference.

# Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Tinembart et al. and Chu et al. do not teach adding beet pulp to their compositions, as instantly claimed. However, Burkhalter et al. teach that beet pulp is the most common source of fiber added to commercial dog diets (page. 1979, left column, lines 8-10 after the table description). Sunvold et al. teach that diets containing moderately fermentable fiber provide fermentation end products that may be important in maintaining the health of the gastrointestinal tract of the cat, and beet pulp represents a moderately fermentable fiber source (Abstract; pg. 2335, left column, last sentence; pg. 2338, left column, lines 40-55 without counting spaces). Fahey et al. teach beet pulp levels up to 7.5% of diet DM appear acceptable as a dietary fiber source in a meat-based canine diet (Abstract). Sunvold '258 teach beet pulp is a fermentable fiber which intestinal bacteria present in the animal can ferment to produce significant quantities of short-chain fatty acids (col. 3, Il. 48-54). Jezek et al. teach the production of soluble dietary fibers from sugar beet pulp (Title and Abstract). Desforges et al. teach water-soluble fiber obtainable by treating sugar beet with water free from chemical reagents at

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ambient temperature and at an elevated temperature (Abstract). Desforges et al. further teach that commercial sources of dietary fiber from sugar beet pulp are known, wherein araban is one example of a fraction of the soluble fiber from sugar beet, and water-soluble beet fiber is also found in beet molasses (col. 1, I. 55 to col. 2, I. 5). Desforges et al. also teach that soluble sugar beet fiber has cholesterol lowering properties (i.e., hypocholestrolaemic effect), and a beneficial effect on blood glucose and mineral availability (col. 2. II. 13-17).

### Finding of prima facie obviousness

### Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add beet pulp fiber to the composition of Tinembart et al. because beet pulp fiber is well-known as a commercial source of dietary fiber for use in pet foods, and soluble beet fiber has cholesterol lowering properties (i.e., hypocholestrolaemic effect), and a beneficial effect on blood glucose and mineral availability, as reasonably taught by Desforges et al. Also, one of ordinary skill in the art would have been motivated to package the compositions in specially designed packs, or kits, for the veterinarian or keeper to administer the predetermined dosage at predetermined intervals, as reasonably taught by Tinembart et al. With regard to the instantly claimed kits comprising a plurality of compartments, it would have been *prima facie* obvious for one of ordinary skill in the art to provide a kit comprising multiple compartments in order to have several dosages within one pack or kit, which need to be administered according to a dosage scheme, as taught by Tinembart et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### Response to Arguments

Applicant's arguments are the same as above. Therefore, the examiners response above is incorporated herein by reference.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Contact Information

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Nathan W. Schlientz whose telephone number is

(571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM.

Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

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USPTO Customer Service Representative or access to the automated information

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NWS

/John Pak/

Primary Examiner, Art Unit 1616